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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/281,760      03/30/99      LAWTON      R      241/08

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EXAMINER

EWOLDT, G

ART UNIT

PAPER NUMBER

1644

16

DATE MAILED:

10/24/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/281,760

Applicant(s)  
Lawton et al.

Examiner  
Gerald Ewoldt

Group Art Unit  
1644



☒ Responsive to communication(s) filed on Aug 1, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-115 is/are pending in the application.

Of the above, claim(s) 3-5, 12-14, 18-20, 24-26, 31-33, 38-40, and 44-115 are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1, 2, 6-11, 15-17, 21-23, 27-30, 34-37, and 41-43 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6, 14, 15

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

#### DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 1-2, 6-11, 15-17, 21-23, 27-30, 34-37, and 41-43, in Paper No. 13, is acknowledged.

2. A telephone call was made to Richard San Pietro on 9/29/00 to indicate that the sequence election was considered nonresponsive. At that time Mr. San Pietro elected SEQ ID NO:5 as the specific sequence to be examined.

3. Claims 3-5, 12-14, 18-20, 24-26, 31-33, 38-40, and 44-115 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions. Claim 5 is withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected species.

Claims 1-2, 6-11, 15-17, 21-23, 27-30, 34-37, and 41-43 are being acted upon.

4. The prior art search has been expanded to include the peptides CPEGYRYNLKSKSC, SPEGYRYNLKSKSSE, and LREVEYRYALQMEQLN.

5. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 6-11, 15-17, 21, 23, 27-30, 34-37, and 43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

A specific binding protein which specifically binds to native canine free or B cell-bound IgE, and does not bind to IgE when the IgE is bound to a receptor on a mast cell, including an IgE expressed on the surface of a canine B cell and a specific binding protein which comprises an antibody which binds SEQ ID NOS:4 or 5,

does not reasonably provide enablement for the composition or method above further comprising:

A) a specific binding protein which specifically binds a peptide comprising a leucine positioned two peptide bonds away from a tyrosine-arginine pair (claim 6),

B) a specific binding protein which specifically binds a peptide comprising SEQ ID NOS:1-3 (claim 7),

C) an antibody ...raised to ... a peptide ... wherein said peptide consists of from 5 to 71 amino acids (claim 11).

D) a specific binding protein ... comprising ... a leucine positioned two peptide bonds away from a tyrosine-arginine pair (claim 27 and 34),

E) an antibody ...raised to ... a peptide ... which comprises SEQ ID NO:5, or a conservative variant thereof (claim 21),

F) a specific binding protein ... comprising ... a leucine positioned two peptide bonds away from a tyrosine-arginine pair (claim 27).

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation. The scope of the claims are not commensurate with the enablement provided by the disclosure with regard to the breadth of the compositions encompassed by the claims.

The specification discloses only that the claimed binding protein (an antibody) binds: soluble and ELISA solid phase native IgE, peptides consisting of SEQ ID NOS: 4 and 5, and presumably the 71 amino acid peptide which was used in the immunizations that produced the antibody. The specification provides insufficient working examples that the claimed specific binding protein actually binds all ~1,600 possible epitopes encompassed by the claim (20 amino acids X 20 amino acids X 4 configurations). Lederman et al. (1991) (see page 1176 last paragraph - page 1177 first paragraph) teaches that a single amino acid change in an epitope can ablate antibody binding, thus demonstrating a high degree of unpredictability in the determination of just which peptides will be bound by a particular binding protein. Additionally, Abaza et al. (1992) teaches that any changes to a protein or peptide, **even outside a known binding site** (see page 443 last paragraph - page 444 first paragraph) can ablate antibody binding. The reference teaches that peptides or proteins of different lengths, each comprising a known epitope (or binding site) may or may not be bound by a particular binding protein. Therefore, it cannot be known without testing each possible variation of the peptide whether said binding protein will bind said peptide, thus demonstrating that an undue amount of experimentation would be required to practice the invention as claimed. Further, the recitation of "conservative variants" of SEQ ID NO:5 encompasses a virtually unlimited number of peptides and proteins which would again, given the unpredictability of the art as demonstrated by the

references, would require an undue amount of experimentation to practice the invention as claimed.

*In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Thus, in view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

7. Claims 1-2, 6-10, 17, 23, 27-30, 34-37, and 43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

There is insufficient written description to show that Applicant was in possession of a "specific binding protein", other than an antibody, which binds the recited epitopes. The specification fails to even define the term, other than as an antibody or fragment thereof, except as "recombinant molecules capable of binding a specific peptide". While recombinant molecules are known in the art, none with "specific binding" capability are disclosed in the specification. The specification defines "specific binding" only vaguely as "greater binding affinity than background". Thus, the specification fails to even adequately define the claimed invention (other than as an antibody) therefore one of skill in the art would conclude that the specification fails to disclose a representative number of species to describe the claimed genus. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

8. Claims 41 and 42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the monoclonal antibody 8H.8 is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35

U.S.C. 112, first paragraph, may be satisfied by a deposit of the pertinent hybridoma. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a U.S. patent.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

The current address of the ATCC is as follows:  
American Type Culture Collection, 10801 University Blvd.,  
Manassas, VA 20110-2209.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 7-8, 11, 15-17, 21-23, 27-30, and 34-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

A) In claim 7, the word "blank" has not been defined and thus renders the claim ambiguous and indefinite. It is suggested that Applicant use "Xaa" to denote "any amino acid".

B) In claims 11-12, 21, 27-28, and 34-35, the recitation of the term "an antibody ... which is raised to ... a peptide" renders the claims ambiguous and indefinite. Said term has no specific well-known meaning within the art and has not been defined in the specification.

C) In claim 11, the "antibody of claim 9" has no antecedent basis in claim 9.

D) In claims 17, 23, 30, 37, and 43, the recitation of the term "recombinant binding molecule" renders the claims ambiguous and indefinite. Said term has no specific well-known meaning within the art and has not been defined in the specification.

E) In claim 41, the recitation of the laboratory designation "8H.8" renders the claims ambiguous and indefinite. Applicant is advised to recite the ATCC designations for the hybridoma and antibody it produces.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims are 1-2 and 6-11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 95/31728 (1995).

WO 95/31728 teaches a specific binding protein (monoclonal antibody) which specifically binds to a purified peptide comprising a leucine positioned two peptide bonds away from a tyrosine-arginine pair (including SEQ ID NOS:1-3) wherein one of the intervening amino acids comprises an aromatic ring (see entire document, particularly page 6 lines 16 and 27 and page 9 lines 3-6). Note that claims 1 and 2 are included in the rejection because the antibody of the reference teaching meets the structural limitations of the claims, i.e., it is a specific binding protein, and at least one of the functional limitations of the claims, i.e., it binds a specific sequence that is defined in the specification as canine specific. The Office does not have the facilities to ascertain whether or not the reference binding protein meets the additional limitation of binding free or B cell bound IgE, but not mast cell bound IgE. Therefore, absent any evidence to the contrary, the specific binding protein of the reference is considered to be the specific binding protein of the claims.

13. Claims are 1-2 and 6-11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5,321,123 (1994).

The '123 patent teaches a specific binding protein (monoclonal antibody) which specifically binds to a purified peptide comprising a leucine positioned two peptide bonds away from a tyrosine-arginine pair (including SEQ ID NOS:1-3) wherein one of the intervening amino acids comprises an aromatic ring (see entire document, particularly Table 1, PSP-7 and 16, and column 17, lines 48-49). See note concerning claims 1 and 2 in paragraph 12, *supra*.

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 1 and 2 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,428,133 (1995) in view of DeBoer et al. (1993)

The '133 patent teaches a specific binding protein which specifically binds free IgE but does not bind to IgE bound to a receptor on mast cells, said specific binding protein being useful for the treatment of IgE mediated allergic diseases (see particularly column 4, lines 7-13).

The reference teaching differs from the claimed invention in that it does not teach a canine specific binding protein.

DeBoer et al. teaches a canine specific anti-IgE antibody and that IgE mediated allergic diseases pose a significant health problem in dogs (see particularly page 184, paragraph 2)

From the teachings of the references it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to produce an anti-IgE specific binding protein for the treatment of allergic disease, as taught by the '133 patent, said binding further being canine specific, as taught by DeBoer et al. One of ordinary skill in the art would have been motivated to make said canine specific binding



protein because IgE mediated allergic diseases pose a significant health problem in dogs, as taught by DeBoer et al.


16. No claim is allowed.

17. The 8H.8 antibody appears to be free of the prior art.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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